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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,975	11/19/2003	Nnochiri N. Ekwuribe	9233.8DV3	7557
20792	7590	11/05/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			GITOMER, RALPH J	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	
			1651	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,975

Applicant(s)

EKWURIBE ET AL.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-35, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-35, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The IDS received 8/26/04 and the preliminary amendment received 11/19/03 have been entered and claims 23-35, 64, 65 are currently pending in this application. The claims have been renumbered according to Rule 1.126. The parent application, 09/134,803 is not currently available to the examiner so some of the references in the IDS have not been considered. Please inform the examiner as to any related applications and update the present specification regarding continuing information.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 23-32, 34, 64, 65 are rejected under 35 U.S.C. 102(a) as being anticipated by Ekwuribe.

Ekwuribe (5,681,811) entitled "Conjugation Stabilized Therapeutic Agent Compositions, Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" teaches in the abstract, therapeutic agents conjugated to a polymer with lipophilic and hydrophilic moieties. A variety of drugs are listed including compounds that activate opioid receptors. Polyalkylene glycol moieties are taught. In column 8 a variety of fatty acid moieties are employed. In column 13 PEG conjugates are shown with fatty acids. See the claims.

All the features of the present claims are taught by Ekwuribe for the same function as claimed.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwuribe.

Ekwuribe (5,681,811) entitled "Conjugation Stabilized Therapeutic Agent Compositions, Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" teaches in the abstract, therapeutic agents conjugated to a polymer with lipophilic and hydrophilic moieties. A variety of drugs are listed including compounds that activate opioid receptors. Polyalkylene glycol moieties are taught. In column 8 a variety of fatty acid moieties are employed. In column 13 PEG conjugates are shown with fatty acids. See the claims.

Claim 33 specifies particular amphiphilic oligomers where Ekwuribe describes amphiphilic oligomers in general terms.

It would have been obvious to one of skill in this art at the time the invention was made to select any known amphiphilic oligomers as taught by Ekwuribe because no criticality is seen in the selection of the oligomers. Ekwuribe teaches a large variety of such oligomers will work.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 33, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 24, "characterized in that" may be intended to be "wherein". Claim 24 is unclear as written, "activity the without". In claim 33 the Markush group is directed to peptides but not all the cited members are peptides.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Summerton (6,030,941) teaches conjugated drugs.

Bodor (6,440,933) teaches conjugated drugs.

Ekwuribe (6,703,381) is the parent patent.

Ekwuribe (US 2003/0228275 A1) teaches oligomer conjugates.

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Ekwuribe (US 2004/0180840 A1) teaches conjugated drugs.

Ekwuribe (6,191,105) teaches conjugated drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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